

**REMARKS**

Claims 2, 4, 6, 9, 14-19, 21-24, and 27 are pending. No amendments have been made by way of the present submission, thus, no new matter has been added. Additionally, no new issues have been raised which would require additional search and/or consideration on the part of the Examiner. In the event that the present submission does not place the application into condition for allowance, entry thereof is respectfully requested as placing the application into condition for allowance.

Interview dated August 30, 2006

Applicants take this opportunity to thank Examiner Cook and Supervisory Examiner Le for the courtesies extended during the Personal Interview conducted on August 30, 2006. The present response places the arguments presented at the Personal Interview on the record. In view of the following remarks, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. §103(a)

The Examiner has rejected claims 2, 4, 6, 16, 17, 18, 22, 23, 24 and 27 under 35 U.S.C. §103(a) as being obvious over Gorski et al. (*Clinical Chemistry*, 43(1):193-195, 1997) in view of Maatman et al. (*Biochem. J.* 288:285-290, 1992) and Simon et al. (*J. Biol. Chem.* 272(16):10652-10663, 1997).

The Examiner has also rejected claim 9 under 35 U.S.C. §103(a) as being obvious over Gorski et al. in view of Maatman et al. and Simon et al., and further in view of Kimura et al. (*J. Biol. Chem.*, 266(9):5963-5972, 1991).

The Examiner has also rejected claims 19 and 21 under 35 U.S.C. § 103(a) as being obvious over Gorski et al. in view of Maatman et al. and Simon et al., and further in view of Galaske et al. (*Pflugers Archives Euro. J. Physiol.*, 375(3):269-277, 1978).

Lastly, the Examiner has rejected claims 14 and 15 under 35 U.S.C. § 103(a) as being obvious over Gorski et al. in view of Maatman et al. and Simon et al., and further in view of Zuk et al. (United States Patent No. 4,281,061).

Applicants respectfully traverse each of the above rejections.

As a preliminary matter, Applicants hereby incorporate by reference all arguments of record. However, in the present response Applicants would like the Examiner to focus her attention on the Declaration pursuant to 37 C.F.R. §1.132, which was submitted with the response of March 20, 2006. A duplicate copy of this Declaration is attached hereto for the Examiner's convenience.

#### Discussion of Declarative Evidence

On March 20, 2006, Applicants submitted a Declaration executed by Dr. Takeshi Sugaya (execution date March 14, 2006). The Examiner commented on the Declaration in the paragraphs bridging pages 12 and 13 of the outstanding Office Action. However, Applicants respectfully request that the Examiner reconsider this Declaration.

In the Office Action the Examiner has cited to a particular case (*In re DeBlauwe*, 736 F2d 699, 705, 222 USPQ 191, 196 (Fed Cir 1984), however, Applicants submit that this case cannot be used to support the Examiner's position. *In re DeBlauwe* states that attorney

arguments cannot take the place of evidence on the record. Applicants agree and therefore request that the Examiner reconsider the Declaration of record.

This Declaration is important since even if the Examiner has hypothetically established a *prima facie* case of obviousness, a point not conceded by Applicants, the presently claimed subject matter still achieves unexpectedly superior results compared to the prior art. For instance, even assuming that H-FABP and L-FABP are suggested by the prior art and should be tested for when attempting to diagnose or prognose kidney disease, the results achieved are not equivalent. That is, as shown in the Declaration, urinary levels of L-FABP are much more elevated over time after administration of contrast media compared to urinary levels of H-FABP. This is evident from a review of the data. For instance, the mean values with standard deviation (S.D.) are shown in Table 1 of the Declaration. The same data is shown graphically in Figure 1 (please note that in Figure 1, the upper bar only is described for S.D.).

Thus, even if the elevation of both of H-FABP and L-FABP in renal disease would be suggested or expected (which Applicants do not believe is true) it would still be unexpected that the levels of L-FABP would be so significantly elevated compared to levels of H-FABP. Therefore, even assuming the Examiner has established a *prima facie* case of obviousness, a point not conceded, the unexpectedly superior results demonstrated in the Declaration render any hypothetical *prima facie* case of obviousness moot.

In summary, Applicants have demonstrated that the presently claimed subject matter is unexpectedly superior to the cited art. Therefore, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

If the Examiner has any questions or comments, please contact Craig A. McRobbie (Registration No. 42,874) at the office of Birch, Stewart, Kolasch and Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: October 4, 2006

Respectfully submitted,

for

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Attachment: copy of Declaration under 37 C.F.R. §1.132 (submitted previously on March 20, 2006)